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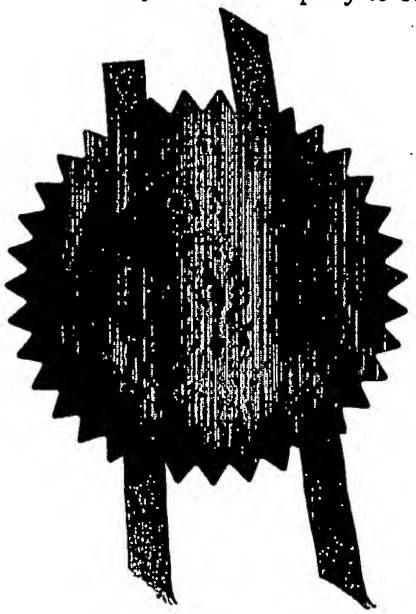

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2. Patent application number
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3. Full name, address and postcode of the or of each applicant *(underline all surnames)* — 3M INNOVATIVE PROPERTIES COMPANY,
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Minnesota 55144-1000,
United States of America

Patents ADP number *(if you know it)* — 07805310001

If the applicant is a corporate body, give the country/state of its incorporation — U.S.A. State of Delaware

4. Title of the invention — DOSE COUNTER FOR DISPENSERS

5. Name of your agent *(if you have one)* — LLOYD WISE

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)* — Commonwealth House, 1 – 19 New Oxford Street, London, WC1A 1LW

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# DOSE COUNTER FOR DISPENSERS

This invention relates to dose counters for dispensers and in particular to dose counters for use with an inhaler comprising a container for medicament equipped with a reciprocal actuation means, such as a valve, to dispense a dose of medicament from the container.

Since the metered dose pressurised inhaler was introduced in the mid-1950's, inhalation has become a widely used route for delivering bronchodilator drugs and steroids to the airways of asthmatic patients. More recently, inhalation from a pressurised inhaler has been a route selected for administration of other drugs which are not primarily concerned with treatment of a bronchial malady.

A metered dose inhaler generally comprises a container equipped with a metered dose dispensing valve. The container contains a pressurised aerosol formulation which generally comprises a liquefied propellant, a surfactant, a medicament and optionally a solvent. The medicament may be in the form of a dispersion or in solution in the aerosol formulation. Metered dose dispensing valves generally comprise a valve stem which is moved inwardly with respect to the container to dispense a metered dose of aerosol formulation. The metering chamber of the valve is normally open to receive contents from the container when the valve is in its rest position although some designs of valve may only open the metering chamber as the valve stem is returned or when it is depressed to fire. The valve stem is generally biased to its rest position by means of a return spring.

Basic metered dose inhalers, normally referred to as press-and-breathe inhalers, comprise a generally cylindrical housing, a mouthpiece and a nozzle block contained within the housing. The aerosol container is inserted within the housing with the valve stem in the nozzle block. In use, a patient places their lips over the mouthpiece and presses the base of the aerosol container

causing the container to move relative to the valve stem to fire a dose of medicament through the mouthpiece.

More sophisticated types of inhaler automatically fire the aerosol in response to inhalation. Such devices generally comprise a mechanism that can apply a firing force to the aerosol container with a trigger mechanism which prevents the firing force from acting on the container until inhalation is detected through the mouthpiece.

One of the disadvantages arising from the use of such known inhalers is that the patient cannot readily determine the amount of medicament in the container at any given time. In an extreme case this could mean that the patient in need of a dose of medicament will find that the inhaler will not dispense a dose because its contents have already been exhausted. There have been numerous proposals for dose counters to be used with pressurised aerosol inhalers. It has proved to be difficult to produce such a dose counter which is both economic and reliable. One of the problems associated with such dose counters is that they should count a single dose only when a dose of medicament has been dispensed. Thus, the count should not be triggered if the valve stem is not sufficiently depressed to fire the valve and it should not count more than one dose during a firing cycle e.g. if the return cycle of the valve is interrupted. Furthermore, the counter must be sufficiently sturdy so that it will not alter the count when the inhaler is subject to the rigors of being carried in a pocket, bag etc. Furthermore, the counter must have a sufficient life to withstand the number of doses to be dispensed from the aerosol container. Furthermore, the dose counter must be able to compensate for the normal manufacturing variation in the production of the inhalers which may result in a slightly different length of travel of the valve stem before the valve is triggered.

Various designs of dose counter have been proposed in which a counter ring or indexing mechanism is advanced in two stages; a first counting motion occurring during the relative motion between the container and the valve stem to dispense the medicament and a second counting motion occurring when the inhaler is returned to its rest position. Examples of such designs are disclosed in WO98/56444, WO98/56445, WO98/56446, WO00/59806, WO02/69252, WO02/69253, EP269496, EP949584 and US 5,611, 444.

US 4565302 discloses a dosing mechanism in the form of a manually operated, single-acting piston pump which dispenses a metered dose of substance e.g. in atomised form, during each activating stroke, which dosing mechanism comprises a counter. A counting ring which is fixed so that it cannot move in the axial direction of the actuating stroke is mounted for rotary motion on a base part of the dosing mechanism and is advanced during the actuating stroke by an indexing device. The indexing device and counting ring have correspondingly bevelled ribs which co-operate during the actuating stroke to rotate the counting ring. The counting ring may be provided with a safety catch which comprises a notched star-shaped portion in the form of external teeth on the base which co-operate with resilient plastic strips projecting inwardly from the counting ring. The plastic strips co-operate with the notched star in the manner of pawls. As a result of the shape of the teeth which comprise relatively shallow sloping tooth profiles with an asymmetric notch in the tooth gullet it is assured that the plastic strips automatically rotate the counting ring to complete a count. The safety catch also prevents backward rotation of the counting ring.

The present invention provides an alternative construction of dose counter which is particularly suitable for use with pressurised aerosol inhalers.

According to the invention there is provided a dose counter for use with an inhaler comprising a container for medicament equipped with a reciprocal

actuation means to dispense a dose of medicament therefrom, the dose counter comprising:

a fixed ratchet member,

a trigger member constructed and arranged to undergo reciprocal movement co-ordinated with the reciprocal movement between the actuation means and the container, said reciprocal movement comprising an outward stroke and a return stroke, a counter member constructed and arranged to undergo a predetermined counting movement each time a dose is dispensed, the counter member being biased towards the ratchet and trigger members and being capable of counting motion in a direction generally orthogonal to the direction of reciprocal movement of the trigger, the counter member comprising:

a first region for interaction with the trigger which comprises at least one inclined surface which is engaged by the trigger during its outward stroke causing the counter member to undergo counting motion,

a second region for interaction with the ratchet member which comprises at least one inclined surface which is engaged by the ratchet member during the return stroke of the trigger causing the counter member to undergo further counting motion to complete said predetermined counting movement.

The counter mechanism of the invention is designed to allow precise counting by advancing the counter member, which is normally in the form of a counter ring, partly on the outward stroke of the trigger and partly on the return stroke. In the case of a conventional inhaler, the outward stroke of the trigger will correspond to the depression of the valve stem within the container causing firing of the valve and the return stroke of the trigger will correspond to the return of the valve stem to its rest position under the influence of its return spring, allowing metering of the next dose. However, the invention is equally

applicable to other reciprocal actuation means e.g. a valve with a stem that when depressed both meters the contents and fires on its outward stroke or a valve which both meters the contents and fires on its return stroke.

The dose counter is preferably constructed and arranged such that the counter member is urged to return to its previous count position if the outward stroke of the trigger is interrupted and reversed. The device is preferably constructed and arranged such that if the return stroke of the trigger is interrupted and reversed the counter member will return to its position at the end of the previous outward stroke of the trigger.

Some allowance for lost motion is inherent in the construction of the dose counter due to the counter member being resiliently biased towards the ratchet and trigger members and also because the trigger member disengages from the counter member during the return stroke. The lost motion allows the counter mechanism to accommodate movement of the reciprocal actuation means and hence the trigger, well beyond that required to dispense the dose and advance the counter without causing the counter to miscount.

The dose counter does not require delicate parts that easily break or distort and may be constructed of robust parts which may readily be fabricated from plastics material.

In the following discussion the dose counter will be described with reference to its use with a conventional press-and-breathe inhaler. In such an arrangement the container will be positioned vertically with the valve stem oriented downwards and located in a nozzle block. The inhaler is actuated by moving the container downwardly. However, it will be readily appreciated that the dose counter may be adapted for use with other devices having a reciprocal actuation means, such as dry powder inhalers, pump spray devices, and other liquid spray devices.

In preferred embodiments, the counter member of the dose counter is in the form of a ring. The counter ring is mounted for rotation within a housing and has markings e.g. integers, on the cylindrical side surface which may be viewed through a window in the housing to determine the count. The upper surface of the counter ring comprises a first region for interaction with the trigger and a second region for interacting with the ratchet member. Each region comprises a series of inclined surfaces that defines a series of teeth. In one embodiment of the invention the counting ring comprises a first set of teeth for engagement with the trigger and a second set of teeth for engagement with the ratchet member. In a second embodiment of the invention the counter ring comprises one set of teeth which are engaged by both the trigger and ratchet member.

The ratchet member comprises at least one projection or tooth which is fixed e.g. to a housing of the dose counter. The projection or tooth is conveniently formed in the housing e.g. projecting downwardly from the housing lid. A plurality of ratchet members may be circumferentially spaced to co-ordinate with teeth on the counter ring.

The trigger is generally secured to the valve ferrule and/or container so that it moves therewith when the container is depressed to fire the valve and released to return to its rest position under the influence of the valve spring. The trigger comprises one or more teeth for engagement with the surfaces of the teeth of the counter ring. Thus during its outward stroke the trigger will move downwardly and engage the upwardly facing teeth of the counter ring as the aerosol container is depressed and during its return stroke it will move upwardly away from the counter ring when the aerosol container is released to return to its rest position under the influence of the return spring of the valve.

The counter ring is resiliently biased towards the fixed ratchet member and trigger member i.e. it is biased upwardly. The counter ring may conveniently be biased by a coil spring or leaf spring acting on the bottom of the counter ring.

In the rest position the counter ring is resiliently biased in contact with the ratchet member and the ratchet member is fully engaged in the tooth gullet of a tooth on the counter ring. This engagement prevents rotational motion of the counter ring in either direction.

In a preferred embodiment of the invention the tooth gullet on the counter ring is defined between a vertical surface and an inclined surface or a horizontal surface and a vertical surface, the vertical surface and the ratchet member defining a ratchet to prevent motion of the counter ring in the counting direction. Where present, the inclined surface engages the ratchet member preventing motion in the non-counting direction since the counter ring is biased against the ratchet member. In the rest position the trigger is spaced above the teeth of the counter ring.

As the aerosol container is depressed towards the firing position, downward movement of the container causes downward movement of the trigger such that it contacts an inclined surface of an upraised tooth of the counter ring near the apex of a tooth. There is a horizontal resultant force component due to the contact angle of the trigger and associated inclined surface of the tooth but rotational motion of the counter ring is prevented due to engagement between the ratchet member and associated tooth.

As the container and trigger are depressed further the counter ring is moved downwardly against its resilient bias by compressing the spring. During this further downward movement the ratchet member will remain engaged with the associated tooth preventing motion in the counting direction.

Further depression of the aerosol container, sufficient to cause firing of the valve causes downward movement of the trigger and counter ring to such an extent that the ratchet member becomes disengaged from the associated tooth thereby allowing rotational motion of the counter ring in the counting direction. Further depression of the aerosol container after the firing point causes further downward movement of the trigger as it acts on the inclined surface of the tooth causing rotation of the tooth until such time as the trigger member reaches the tooth gullet. At this limit of travel the counter ring will have completed the first part of its counting motion and it will have moved sufficiently such that the ratchet member is positioned over the inclined surface of the next ratchet tooth.

When the aerosol container is released it returns to its rest position under the influence of the return spring of the valve causing upward movement of the trigger away from the teeth of the counter ring. As the trigger is moved upwardly the counter ring is biased upwardly against the ratchet member. During the initial upward movement of the trigger the ratchet member engages an inclined surface of a tooth and under the influence of the resilient bias there is a horizontal resultant force which causes further rotation of the counter ring in the counting direction. When the aerosol container has moved sufficiently for the metering chamber in the aerosol valve to refill, the counter ring would have moved a sufficient distance in the counting direction so that the next tooth will be facing the trigger. When the aerosol container has returned to its rest position the ratchet member will be fully engaged within the gullet of the next tooth.

It will be appreciated that partial depression of the aerosol container, insufficient to fire the valve, will not result in any motion of the counter ring. After firing, if the aerosol container is partially released without returning to its rest position and then depressed, the counter ring will return to an intermediate position and subsequent release of the aerosol container to

return to its rest position will result in the completion of the counting movement under the influence of the ratchet member. Thus, there is no double counting if there is interference with the return stroke of the trigger.

In a further embodiment of the invention the gullet of the ratchet tooth is defined by two inclined surfaces forming an obtuse or acute angle. As the trigger is moved downwardly to engage the inclined surface it depresses the counter ring allowing the ratchet member to ride up an inclined surface thereby causing rotational motion of the counter ring in the counting direction. If the aerosol container is released prior to firing, the trigger will move upwardly and the counter ring will move upwardly under the resilient bias causing the ratchet member to track down the inclined surface back to the gullet of the tooth thereby rotating the counter ring backwards to its original position.

The counter ring conveniently counts a small number of discrete doses e.g. ten, twenty, thirty doses etc. Counting a large number of doses on a single counter ring would necessitate provision of a correspondingly larger number of teeth which would need to be smaller in order to be accommodated on the counter ring. Since most inhalers contain a greater number of doses e.g. two hundred doses, the dose counter of the invention will generally comprise a second counter ring to provide a "tens" digit or "hundreds" and "tens" digits. A third counter ring may be incorporated to count "hundreds". The second counter ring may conveniently be positioned below the main counter ring and driven such that it is advanced one unit for ten increments of the main counter ring e.g. the second counter ring is advanced each full rotation, half rotation, or third of a full rotation etc of the main counter ring depending on the number of teeth on the main counter ring. The driving may conveniently be achieved by providing internal teeth on the second counter ring which are engaged by a cog which is turned when a lug on the main counter ring intermittently engages the cog during rotations of the main counter ring.

The invention will now be described with reference to the accompanying drawings in which:

Figures 1A to 1H are diagrams showing the principle of operation of one embodiment of a dose counter in accordance with the invention during the various stages of counting a single dose,

Figure 2 represents a schematic diagram of the principle of operation of a further dose counter in accordance with the invention,

Figures 3A to 3D are diagrams showing the principle of operation of a further dose counter in accordance with the invention,

Figures 4A to 4D represent schematic diagrams of the principle of operation of a further dose counter in accordance with the invention,

Figure 5 represents an exploded view of a dose counter operating in accordance with the principle shown in Figures 1A to 1H,

Figure 6 represents a cross-section showing part of a press-and-breathe inhaler incorporating the dose counter of Figure 5,.

Figure 7 represents a counting ring suitable for use in a dose counter operating according to the principle disclosed in Figure 3,

Figure 8 represents a counter ring for a dose counter operating in accordance with the principle disclosed in Figure 4.

Figures 1A to 1H illustrate the operation of a dose counter in accordance with the invention. The dose counter comprises a ratchet member (2) which is fixed e.g. to the housing, and trigger (4) which is fixed to the valve ferrule and/or aerosol container (not shown) to move therewith. The counter ring (not shown completely) comprises a set of teeth (6) for interaction with the trigger (4) and a set of teeth (8) for interaction with the ratchet member (2).

The set of teeth (6) comprise a series of inclined surfaces (10 and 12) defining points (14) and gullets (16). The set of teeth (8) comprise a series of inclined surfaces (18) and vertical surfaces (20) defining points (22) and gullets (24). The set of teeth (6) may conveniently be positioned radially inwardly of the set of teeth (8).

In the rest position shown in Figure 1A the trigger (4) is spaced from the set of teeth (6). The fixed ratchet member (2) is engaged with a tooth (8) with the ratchet member positioned within the gullet (24). The counter ring is resiliently biased upwardly against the ratchet member (2) and rotational motion of the counter ring is prevented in one direction by engagement between the ratchet member and the vertical surface (20) of a tooth and in the other direction by engagement of an inclined surface (18) with the ratchet member.

Figure 1B shows the position of the trigger member (4) during the initial stages of depression of the aerosol container to actuate the valve. Depression of the aerosol container causes downward movement of the trigger to contact the inclined surface (10) of a tooth (6).

Figure 1C shows the position of the components after further depression of the aerosol container. The trigger (4) is further depressed causing depression of the counter ring against the resilient bias. Depression of the counter ring causes the inclined surface (18) of tooth (8) to separate from the ratchet member (2). Rotational motion in the counting direction is still prevented by engagement of the vertical surface (20) with the ratchet member (2).

Figure 1D shows the position of the components at about the firing point of the valve. The trigger has been further depressed causing further downward movement of the counter ring until the ratchet member (2) reaches the point of disengagement with the vertical surface (20). It will be noted that if the

aerosol container is released after movement to the stages of Figures 1C or 1D the counter ring will be urged vertically upwardly under the resilient bias and returned to the position of Figure 1A.

Figure 1E shows a transitional position of the components just after firing the valve. The counter ring is rotating in the counting direction (left to right) since motion is not blocked by the ratchet member (2) under the influence of trigger (4) pressing against the inclined surface (10).

Figure 1F shows the limit of the travel of the counting mechanism with the trigger (4) positioned in the gullet (16) of the tooth (6). This is the position that pertains when the valve is completely compressed.

Figure 1G shows the position of the components as the aerosol container is allowed to return towards its rest position under the influence of the return spring of the valve. The position shown in Figure 1G is just prior to the point where the metering chamber of the valve will be refilled. The trigger (4) has moved vertically allowing the counter ring to move both vertically and in the counting direction. Vertical movement of the counting ring causes the inclined surface (18) of tooth (8) to bear against the ratchet member (2) resulting in a horizontal force component causing further rotation of the counter ring in the counting direction. The trigger (4) tracks up the inclined slope (12). If the aerosol container was depressed again before passing the point shown in Figure 1G, the counting device would return to the position shown in Figure 1F.

As the aerosol container is returned to the rest position, trigger (4) disengages from the tooth (6). The counter ring continues rotation in the counting direction under the influence of a horizontal force component generated as the inclined surface (18) is urged against the ratchet member. The components return to the rest position shown in Figure 1A with the counter ring advanced in the counting direction by one tooth.

Figure 2 is a schematic diagram showing the principle of operation of a further counting device in accordance with the invention.

The counting device comprises a ratchet member (2) fixed to a housing (5) of the dose counter. A counter member (3) is resiliently biased towards the ratchet member (2) by means of leaf springs (38) supported on the base (40) of the housing. Trigger member (4) is attached to the valve ferrule and/or aerosol container (not shown) for reciprocal movement therewith.

The counter member (3) has a single set of teeth formed from inclined surfaces (30, 32) which define points (34) and gullets (36).

The dose counter operates as follows. For complete movement of the aerosol container to fire the valve, the trigger (4) contacts against the first inclined surface (30) of the counter member (3) and causes the counter member (3) to move in the counting direction as well as pushing it down against the spring (38). Meanwhile, the ratchet member (2) is tracking the second inclined surface (32). This embodiment is different to that disclosed in Figure 1 wherein the second inclined surface was vertical so that the tracking motion did not involve any movement of the counter ring in the counting direction. As the trigger in Figure 2 is further depressed, the counter member (3) moves to a position such that the ratchet member (2) passes over the point (34) in the toothed profile. The combined effect of the spring and trigger then causes the counter member (3) to advance until the trigger (4) nestles in the gullet (36) of the toothed profile and the ratchet member (2) passes over the point (34).

Upon release of the aerosol container to return it to its rest position, the trigger (4) moves along the inclined surface (32) away from the gullet (36) and the ratchet member (2) engages the upper part of the inclined surface (30). The counter member is biased against the ratchet member (2) under the influence of the spring (38) causing the counter member to move in the

counting direction. The trigger rides up the inclined surface (32) of the next tooth. When the trigger (2) reaches the top of the inclined surface (32) the combined action of the ratchet member on the inclined surface (30) and the spring causes the counter member to advance until the ratchet nestles in the gullet of the tooth profile. It will be appreciated that this motion beyond a point of no return is relatively quick, depending upon the spring and the interaction of the inclined surfaces rather than any movement of the trigger.

For incomplete movement in the downward stroke of the trigger (4) even where the trigger (4) has engaged the inclined surface (30) but not reached the point of no return, upon the subsequent return stroke the ratchet member (2) engages the inclined surface (32) causing the counter member (3) to move in the direction opposite to the counting direction to restore the counter member to its rest position with the ratchet member (2) resting in the gullet (36).

For incomplete movement in the upward stroke of the trigger (4), the next downward stroke results in the actuating member engaging the inclined surface (32) causing the counter member (3) to move in the opposite direction to the counting direction. Subsequent release of the trigger to its rest position will cause completion of the count.

It is preferred that the counter member is in the form of a ring.

It is preferred that the points of no return coincide with the firing of the dose on the downward stroke and the re-metering of the dose in the metering chamber of the valve on the upward stroke.

Figure 3A to 3D of the accompanying drawings represents schematic diagrams showing the operation of a further device in accordance with the invention. The device shown in Figure 3 is similar to the device shown in Figure 2 in that the counter member comprises a single ring of teeth but in

this embodiment the teeth are formed by a vertical surface and an inclined surface.

Referring to Figures 3A to 3D the counting device comprises a fixed ratchet member (2), a counting ring (3) resiliently biased to the ratchet member and a trigger (4) movable with the aerosol container (not shown). The counter ring (3) comprises a single ring of teeth formed from inclined surfaces (30) and vertical surfaces (31) defining points (34) and gullets (36).

The mode of operation is similar to that described with reference to Figures 1 and 2.

Figure 3A shows the counter in the rest position with the ratchet member fully engaged in a tooth of the counter ring (3) and the trigger member spaced from the counter ring.

Figure 3B shows the counter mechanism in a transitional position corresponding to the firing position of the valve with the counter member depressed to such an extent that the ratchet member (2) has just disengaged from a tooth, and trigger (4) presses against inclined surface (30).

Figure 3C shows the device at the full extent of travel of the valve and trigger member (4) with the trigger member fully engaged within a tooth.

Figure 3D shows the counting device on the point of no return corresponding to the re-metering position of the valve. The trigger (4) is about to disengage from the tooth and the counter member (3) has been urged in contact with the ratchet member (2) under the influence of the biasing means. As the aerosol container returns to its rest position the dose mechanism will return to a position as shown in Figure 3A with the counter ring advanced by one tooth.

For dose counters with one set of teeth on the counter ring, the pitch of the teeth is determined by the size of any numbers to be printed on the ring and

the desire to have a round number of teeth (e.g. twenty) to fit the circumference of the ring. The amplitude of teeth is determined largely by the distance corresponding to the difference in valve displacement between re-metering and firing of the dose. The angle of the first inclined surface (30) needs to be steep enough to allow the ring to be advanced by relative motion with the trigger or ratchet, but must not be too steep to allow the required dimensions of pitch and amplitude to be satisfied. The angle on the second inclined or vertical surface (31,32) is not essential. Since a vertical surface will prevent advancement of the ring until the point of no return is reached, no reverse movement would be necessary to return it if movement is incomplete. The first inclined surface needs to have a projected length on the circumference of the ring that is greater than the corresponding distance separation between trigger and ratchet, which is in turn greater than the corresponding projection of the second inclined surface. This allows the trigger and ratchet to straddle the second inclined surface, but never straddle the first inclined surface.

One possible way of increasing the angle of the inclined surface is to increase the number of teeth on the ring. However, there is a limit to the number of teeth on each ring and to the number of indicia that can be printed on the outside of the ring in a manner which is clearly visible to the user. An alternative way of increasing the slope of the inclined surface is to alter the profile of the teeth to provide a flat region between teeth. The profile of the ratchet member and/trigger may be configured to conform with the respective teeth of the counter ring.

Figures 4A to 4D show the principles of operation of a further embodiment of a dose counter in accordance with the invention. The dose counter is similar to that described with respect to Figures 1A to 1H with the exception that the ring of teeth (8) for co-operation with the ratchet member (2) has a profile defined by inclined surfaces (18), vertical surfaces (20) and flattened portions

(21). The gullet of a tooth (24) is defined between the flat surface (21) and vertical surface (20).

The mode of operation of the dose counter is identical to the dose counter illustrated in Figures 1A to 1H.

Figure 4A represents the dose counter in the rest position, Figure 4B represents the dose counter at about the firing position, Figure 4C represents the dose counter at the full extent of travel of the valve and trigger and Figure 4D represents the dose counter at about the re-metering position of the valve.

Figure 5 of the accompanying drawings represents an exploded view of a dose counter of the invention which operates on the principles illustrated in Figures 1A to 1H.

The dose counter comprises a trigger portion (100) having a cylindrical skirt (102) which is dimensioned to provide a force fit around the ferrule of the valve of an aerosol inhaler. The trigger (100) has three sections (104) of downwardly extending teeth which are configured to correspond to teeth on the counter ring. The trigger (100) will move with the aerosol container and valve ferrule to which it is affixed.

The dose counter comprises a housing consisting of a lower portion (108) and a lid (110). The lower portion (108) comprises a base (112) and a cylindrical sidewall (114). The sidewall (114) includes a window (116) through which the markings on the counter rings may be viewed. The lower portion is provided with feet to locate into the aerosol actuator, as partly shown in figure 6, and may be held in place by having these components designed to snap-fit.

The housing accommodates a "tens" counting ring (120), spring (122), counter ring (124) and cog (126).

Counter ring (124) comprises a cylindrical sidewall (128) upon which the appropriate markings or indicia (not shown) are printed. On its upper surface the counter ring (124) comprises two rings of upstanding teeth. The outer ring of teeth (130) correspond to the teeth (8) in Figure 1. The inner ring of teeth (132) correspond to the teeth (6) in Figure 1. The counter ring (124) additionally comprises two sets of lugs (134) positioned diametrically opposite each other projecting radially inwardly from the interior of the counter ring. The lugs are for engagement with the cog (126), the function of which will be described hereinafter.

The housing lid (110) comprises three fixed ratchet members (136) which extend downwardly from the lid. The ratchet members (136) are configured to mate with the outer ring of teeth (130) on the counter ring, as shown and described in Figure 1. The lid may be firmly secured to the lower housing (108) by projections (138) which provide a snap-fit connection within recesses (140) of the lower portion (108), or may be a press-fit or may be ultrasonically welded onto the lower portion.

Cog (126) comprises an axle (142) which is mounted for rotation with one end in an aperture (144) in the base (112) of the housing and the other end located in a corresponding aperture on the lid (not shown). The teeth of the cog (126) engage with a radially inwardly projecting ring of teeth (146) on the "tens" ring (120).

Figure 6 shows a section through part of a press-and-breathe aerosol inhaler incorporating the dose counter of Figure 5. The display may indicate the number of doses remaining or the number dispensed. The indicia may be suitably alphabetic, numerical, alphanumeric, or colour symbols, providing a sequential count-up or count-down of dispensed doses or providing a more general indication such as "Full" or "Empty". The indicia may be visible through a window (170) in the actuator's cylindrical sidewall; alternatively, the

sidewall may have at least a portion made of a transparent material.The press-and-breathe inhaler comprises a housing (150) having a cylindrical body (152) to accommodate the aerosol container (168)and a mouthpiece (154). A nozzle block (156) is positioned within the housing having an aperture to accommodate the valve stem (158) and a spray orifice (160).

The metering valve of the aerosol container comprises a valve ferrule (162), valve stem (158), metering chamber (164) and return spring (166).

The parts of the dose counter are labelled with the same reference numerals as in Figure 5.

The mode of operation of the dose counter illustrated in Figures 5 and 6 is described in detail with reference to Figure 1. As each dose is dispensed the counter ring (124) will advance by one increment (one tooth) and the appropriate dose may be viewed through the viewing window (170). The "tens" ring will remain stationary until such time as the counter wheel (124) has rotated sufficiently for lugs (134) to engage the cog wheel (126). Further rotation of the counter ring (124) causes the cog (126) to rotate causing corresponding transient rotation of the "tens" ring (120). Thereafter, the "tens" ring will only rotate again when the counter ring has rotated nearly a further 180° i.e. the "tens" ring will only move every ten doses. Whilst the "tens" ring is illustrated to have a smaller diameter than the counter ring, it may be preferable to modify the design to have the "tens" ring larger in diameter. This would allow more space to provide 2 digits on the "tens" ring. Additionally, the "tens" ring could incorporate a downwardly extending shroud to cover the display of the "units" ring upon reaching the "empty" count indication. Further doses dispensed beyond this point would not change the displayed indication, which would be whatever is printed on the "tens" ring.

It may furthermore be desirable to incorporate an alternative air inlet into the actuator to compensate for any slight obstruction of airflow due to the counter

assembly. This may be achieved by forming a series of parallel slots in the base of the actuator.

Figure 7 of the accompanying drawings illustrates a counter ring (124) for a dose counter which operates in accordance with the principles described with reference to Figure 3. The counter ring (124) comprises a single set of teeth defined by inclined surfaces (30) and vertical surfaces (31) forming points (34) and gullets (36).

The constructions of the dose counter is otherwise identical to that disclosed in Figures 5 and 6 with the exception that the teeth (106) of the trigger (100) and the ratchet members (136) of the lid (110) will be configured to conform with the teeth on the counter ring. Also, since the counter ring comprises thirty teeth, there are three sets of lugs (134) for co-operation with the cog (126) to index the "tens" ring (120).

Figure 8 of the accompanying drawings illustrates a counter ring used in a dose counter which operates in accordance with the principles described in Figure 4. The counter ring comprises an outer ring of teeth (130) and an inner ring of teeth (132).

The outer ring of teeth (130) comprise inclined surfaces (18), vertical surfaces (20) and flat regions (24). The inner ring of teeth (132) comprises inclined surfaces (10 and 12).

The remainder of the dose counter is identical to that disclosed with reference to Figures 5 and 6 with the exception that the ratchet members (136) on the lid (110) are configured to mate with the teeth of the outer ring (130). The ring (124) comprises two sets of lugs (134), diametrically opposed, for co-operation with the cog (126) to index the "tens" ring.

CLAIMS

1. A dose counter for use with an inhaler comprising a container for medicament equipped with a reciprocal actuation means to dispense a dose of medicament therefrom, the dose counter comprising:

a fixed ratchet member,

a trigger member constructed and arranged to undergo reciprocal movement co-ordinated with the reciprocal movement between the actuation means and the container, said reciprocal movement comprising an outward stroke and a return stroke,

a counter member constructed and arranged to undergo a predetermined counting movement each time a dose is dispensed, the counter member being biased towards the ratchet and trigger members and being capable of counting motion in a direction generally orthogonal to the direction of reciprocal movement of the trigger, the counter member comprising:

a first region for interaction with the trigger which comprises at least one inclined surface which is engaged by the trigger during its outward stroke causing the counter member to undergo counting motion,

a second region for interaction with the ratchet member which comprises at least one inclined surface which is engaged by the ratchet member during the return stroke of the trigger causing the counter member to undergo further counting motion to complete said predetermined counting movement.

2. A dose counter as claimed in Claim 1 in which the counter member is in the form of a ring.

3. A dose counter as claimed in Claim 2 in which the ring comprises inclined surfaces in the form of at least one set of teeth.

4. A dose counter as claimed Claim 3 in which the ring comprises one set of teeth to interact with the trigger and a second set of teeth to interact with the ratchet member.

5. A dose counter as claimed in Claim 3 in which the ring comprises a single set of teeth which interact with both the trigger and the ratchet member.

6. A dose counter as claimed in Claim 4 or Claim 5 in which the counter member comprises teeth which are defined by two inclined surfaces.

7. A dose counter as claimed in Claim 4 or 5 in which the counter member comprises teeth which are defined by an inclined surface and a vertical surface.

8. A dose counter as claimed in Claim 6 as dependent on claim 4 or Claim 7 as dependent on claim 4 in which there is a flat region between adjacent teeth.

9. A dose counter according to any preceding Claim in which the first region of interaction is longer than the second region of interaction.

10. A dose counter according to any preceding Claim in which an incomplete part of the counting motion associated with the first region of interaction followed by reverse movement of the trigger does not result in a net counting motion.

11. A dose counter according to any preceding Claim in which an incomplete part of the counting motion associated with the second region of interaction followed by reverse movement of the trigger does not result in counting motion beyond said predetermined counting movement.

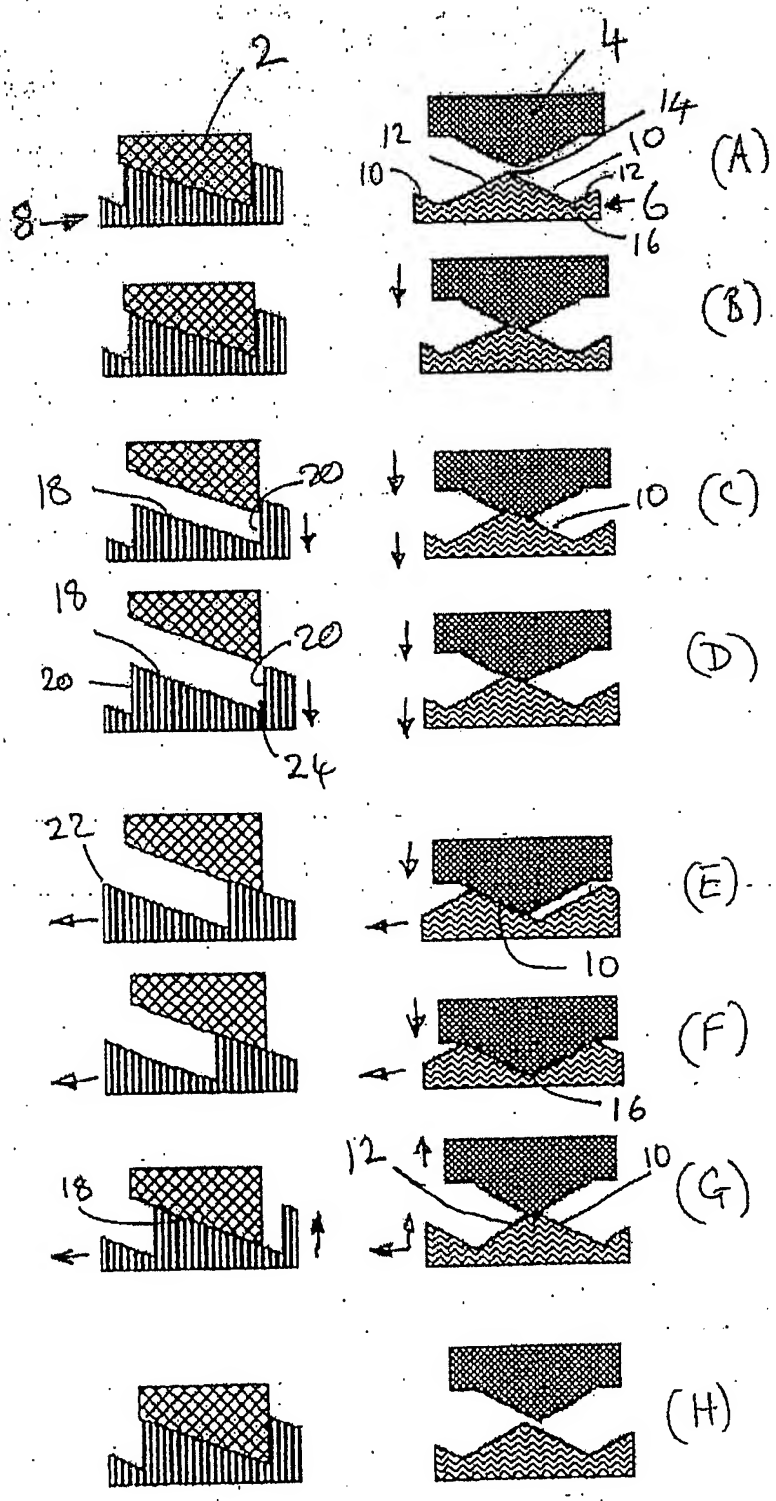
12. A dose counter according to any one of Claims 2 to 11 which comprise a second counting ring which undergoes counting motion in response to counting movement of the counter ring.

13. A dose counter as claimed in any preceding claim which comprises a housing to accommodate the counter member, said ratchet member being fixed to the housing.

14. A dose counter as claimed in which the counter member is resiliently biased by a coil spring or leaf spring.

15. An inhaler incorporating a dose counter as defined in any preceding claim.

16. An inhaler as claimed in Claim 15 in which the trigger is attached to the inhaler canister and/or valve ferrule.


2
4
14
12
10
10
12
6
16
8
(A)
(B)
18
20
10
(C)
18
20
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24
(D)
22
10
(E)
16
(F)
18
12
10
(G)
(H)

Figure 1

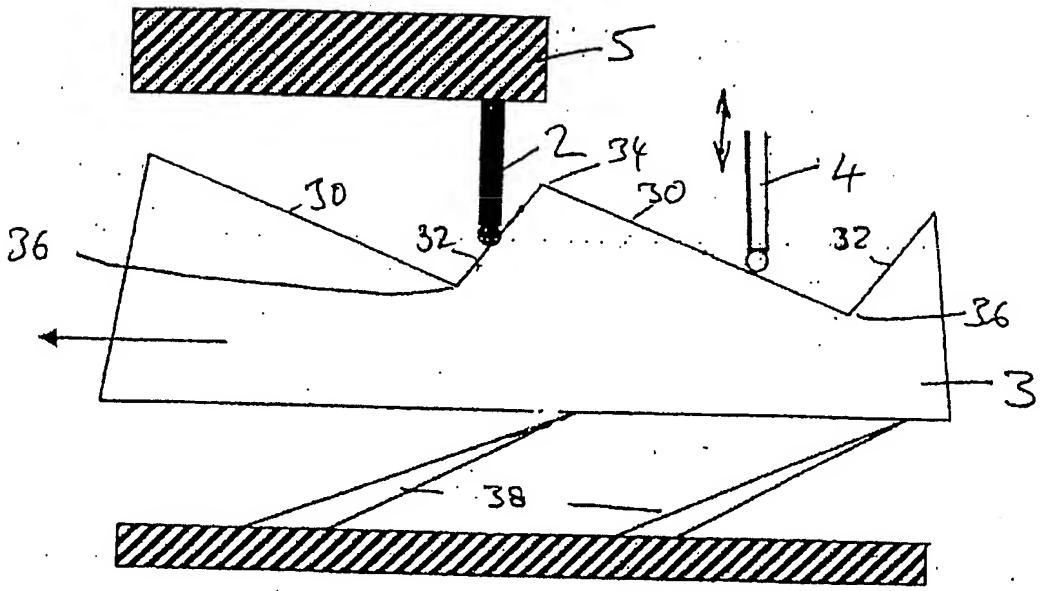



Figure 2

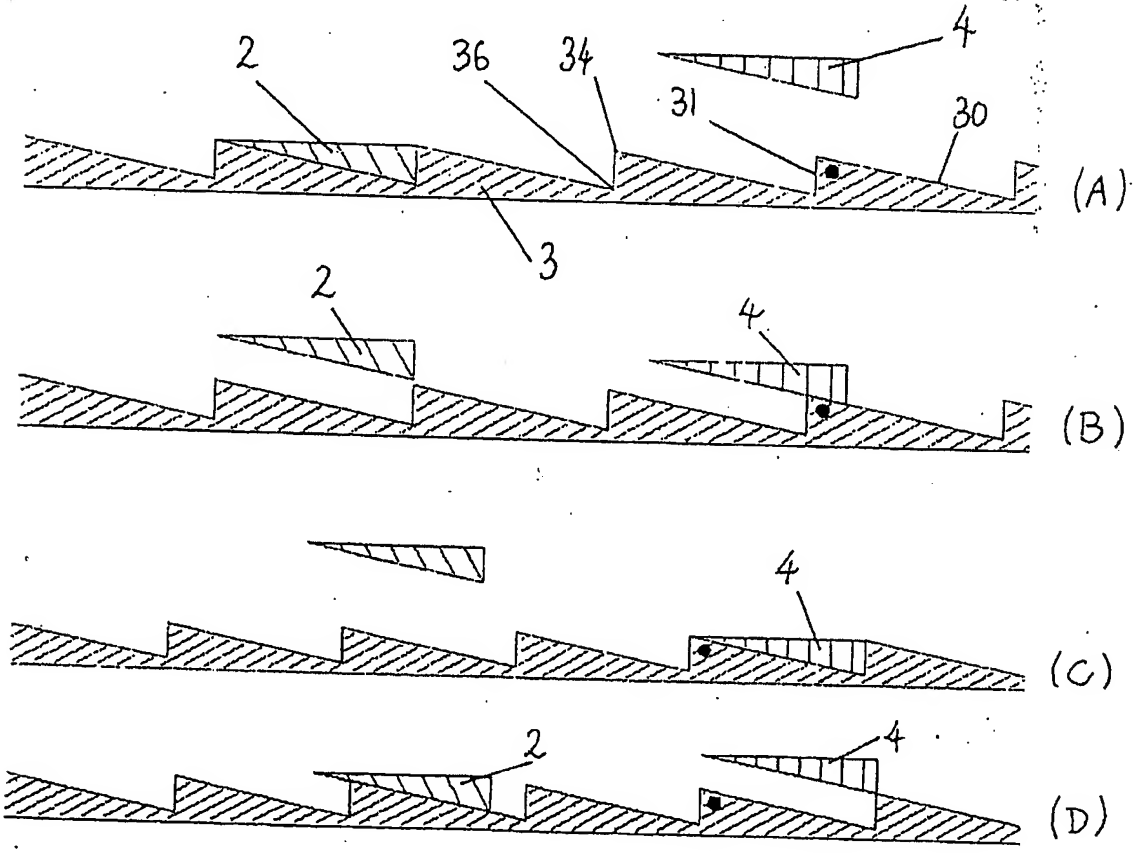



Figure 3

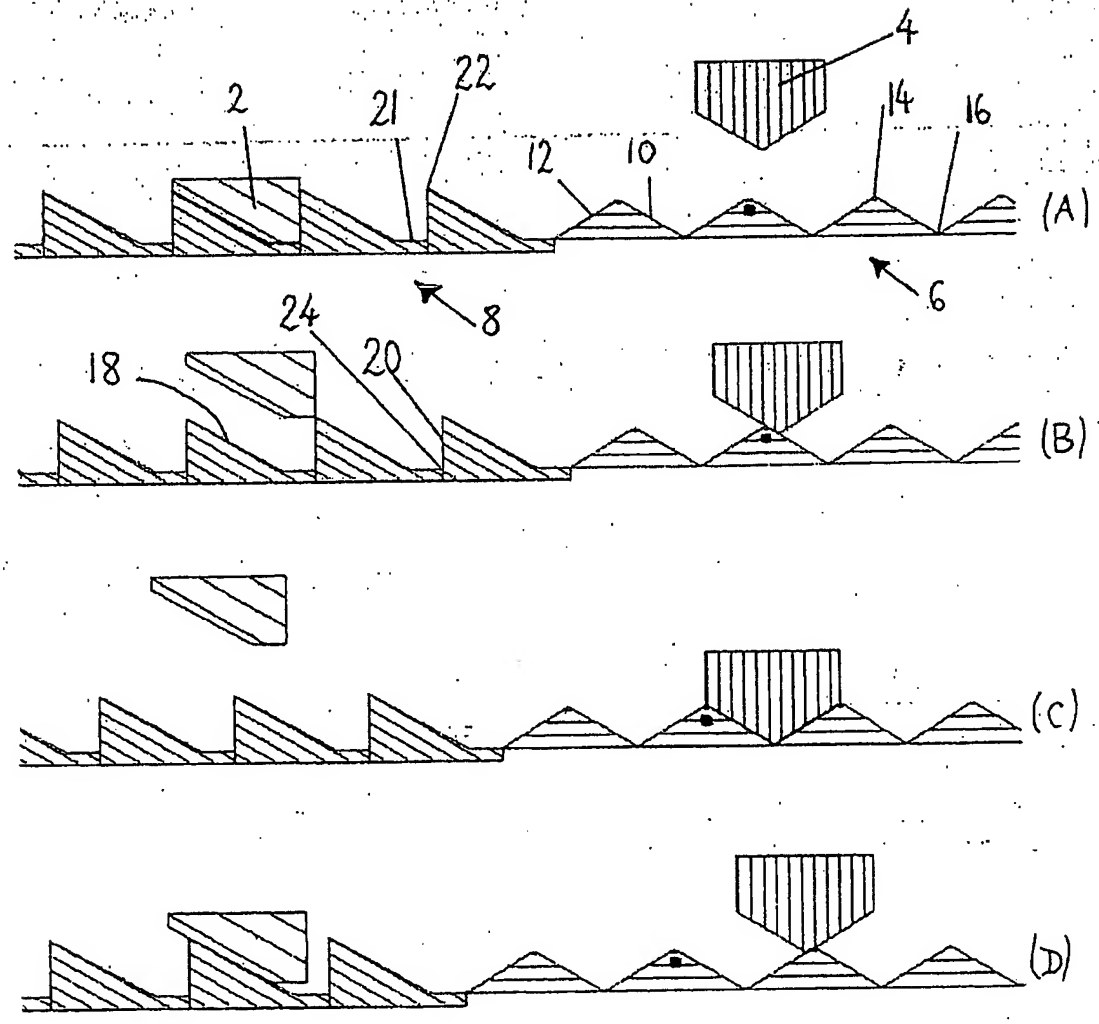
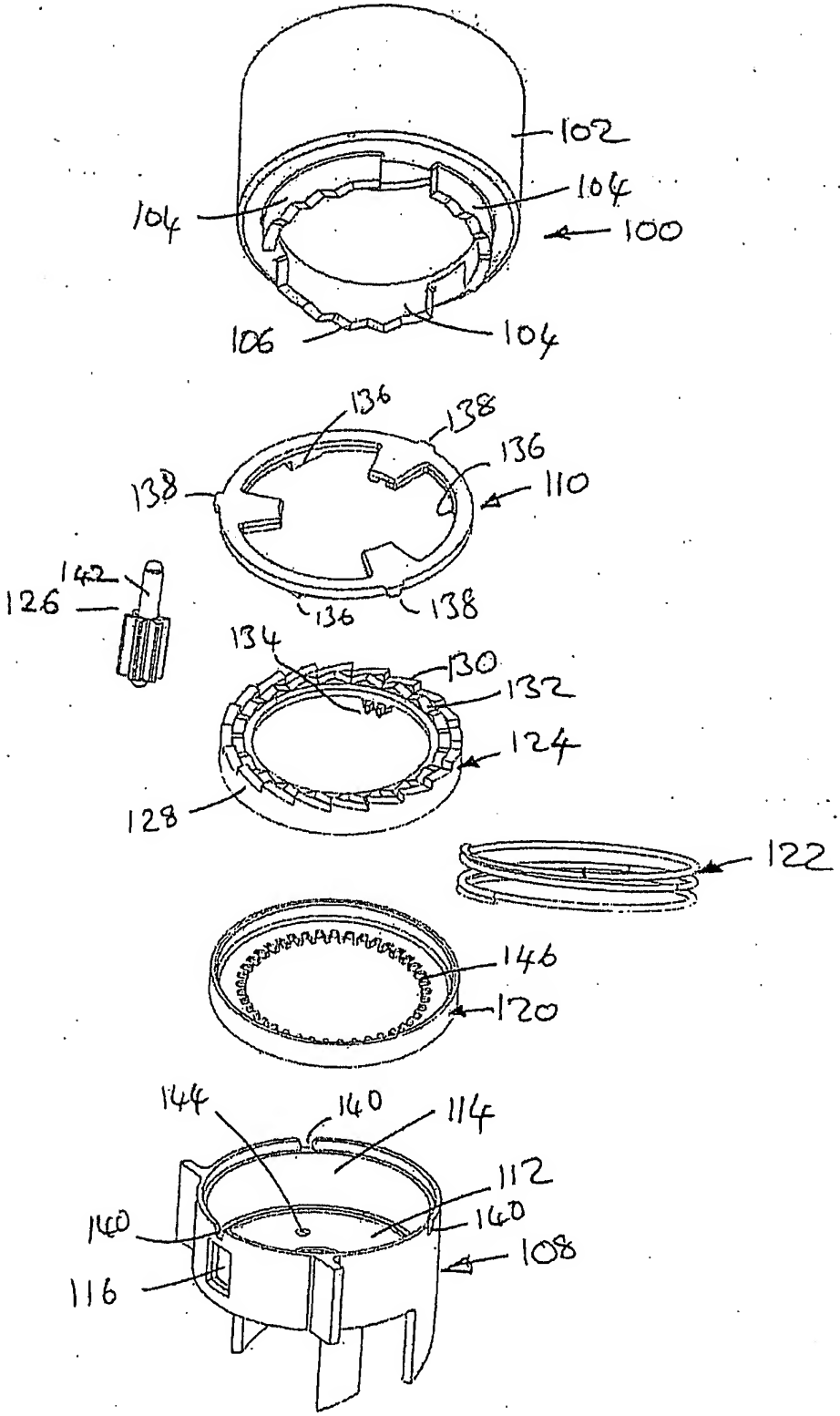



Figure 4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138
136
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144
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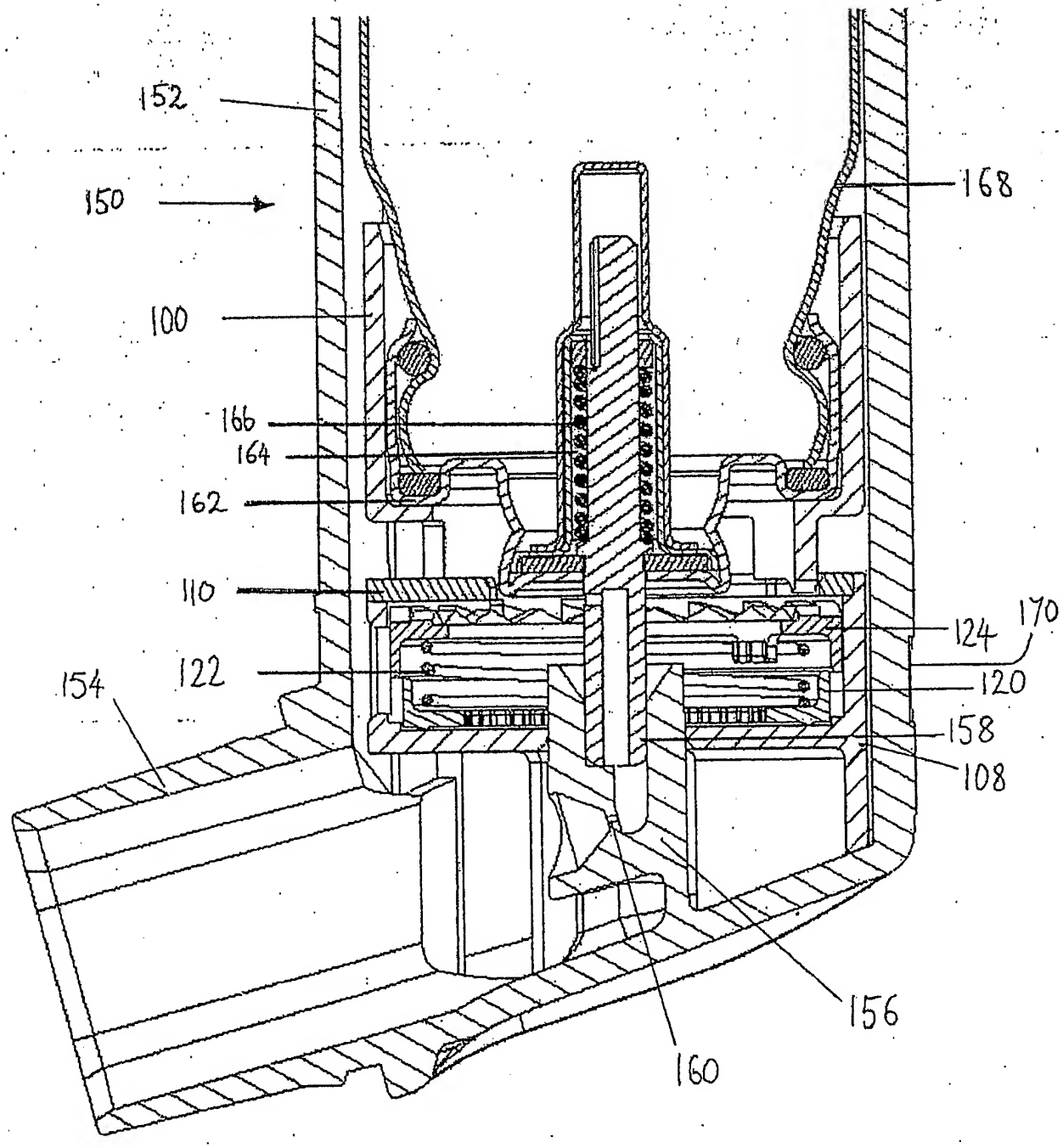
114
112
140
140
108
116

Figure 5


152
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100
166
164
162
110
122
154
168
124
170
120
158
108
156
160

Figure 6

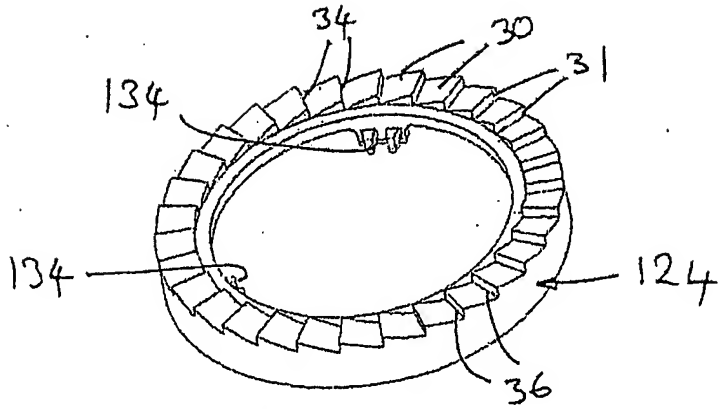


Figure 7

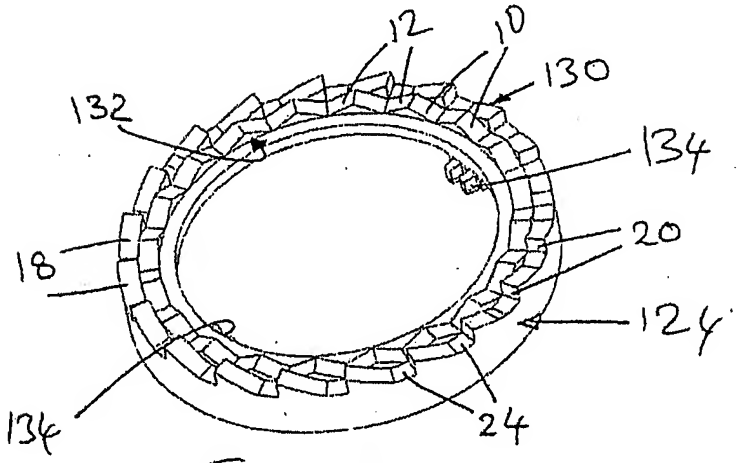


Figure 8